

**APPLICATION FOR
UNITED STATES LETTERS PATENT**

of

MARK ASHBY

for

**DEPTH AND PUNCTURE CONTROL FOR SYSTEM FOR HEMOSTASIS OF
BLOOD VESSEL**

Attorney Docket No. 032005-068

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
Post Office Box 1404
Alexandria, VA 22313-1404
(703) 836-6620

004220"029F2960

**DEPTH AND PUNCTURE CONTROL FOR BLOOD VESSEL
HEMOSTASIS SYSTEM**

Ins. [A1]
B17

The present application is related to, claims priority under 35 U.S.C. § 119 to, and incorporates by reference herein in its entirety, U.S. provisional patent application serial no. 60/156,007, filed September 23, 1999, entitled "System and Method for Determining a Depth of an Incision".

BACKGROUND OF THE INVENTION

Field of the Invention

5 The invention relates to closure systems and methods for blood vessel puncture sites.

Brief Description of the Related Art

10 A large number of diagnostic and interventional procedures involve the percutaneous introduction of instrumentation into a vein or artery. For example, coronary angioplasty, angiography, atherectomy, stenting of arteries, and many other procedures often involve accessing the vasculature through a catheter placed in the femoral artery or other blood vessel. Once the procedure is completed and
15 the catheter or other instrumentation is removed, bleeding from the punctured artery must be controlled.

20 Traditionally, external pressure is applied to the skin entry site to stem bleeding from a puncture wound in a blood vessel. Pressure is continued until hemostasis has occurred at the puncture site. In some instances, pressure must be applied for up to an hour or more during which time the patient is uncomfortably

immobilized. In addition, a risk of hematoma exists since bleeding from the vessel may continue beneath the skin until sufficient clotting effects hemostasis. Further, external pressure to close the vascular puncture site works best when the vessel is close to the skin surface and may be unsuitable for patients with
5 substantial amounts of subcutaneous adipose tissue since the skin surface may be a considerable distance from the vascular puncture site.

More recently, devices have been proposed to promote hemostasis directly at a site of a vascular puncture. One class of such puncture sealing devices
10 features an intraluminal anchor which is placed within the blood vessel and seals against an inside surface of the vessel puncture. The intraluminal plug may be used in combination with a sealing material positioned on the outside of the blood vessel, such as collagen. Sealing devices of this type are disclosed in U.S. Patent Nos. 4,852,568; 4,890,612; 5,021,059; and 5,061,274.
15

Another approach to subcutaneous blood vessel puncture closure involves the delivery of non-absorbable tissue adhesives, such cyanoacrylate, to the perforation site. Such a system is disclosed in U.S. Patent No. 5,383,899.

20 The application of an absorbable material such as collagen or a non-absorbable tissue adhesive at the puncture site has several drawbacks including: 1) possible injection of the material into the blood vessel causing thrombosis; 2) a lack of pressure directly on the blood vessel puncture which may allow blood to escape beneath the material plug into the surrounding tissue; and 3) the inability to
25 accurately place the absorbable material plug directly over the puncture site.

The use of an anchor and plug system addresses these problems to some extent but provides other problems including: 1) complex and difficult application;

2) partial occlusion of the blood vessel by the anchor when placed properly; and
3) complete blockage of the blood vessel or a branch of the blood vessel by the anchor if placed improperly. Another problem with the anchor and plug system involves reaccess. Reaccess of a particular blood vessel site sealed with an anchor and plug system is not possible until the anchor has been completely absorbed because the anchor could be dislodged into the blood stream by an attempt to reaccess.

Such puncture sealing devices are generally used in conjunction with a cannula or arterial dilator which dilates an access tract in the tissue before inserting the sealing device for placing the intraluminal or sealing plug. By using the cannula to dilate the access tract, the sealing device can be easily advanced into the tissue toward the vascular puncture. However, a conventional cannula has either a constant diameter lumen which is sized to closely accommodate a guidewire, or the diameter of the lumen narrows at the distal end. When these conventional cannulas are advanced into the access tract, the cannulas often encounter scar or muscular tissue that requires substantial force to advance the cannula through these layers. In prior conventional cannulae, a cannula which has a constant diameter lumen may enter the vascular puncture while being advanced into the access tract, or the cannula will bounce against a wall of the blood vessel rather than accurately locate the blood vessel wall. Accordingly, the sealing plug may not be accurately placed over the puncture site.

Accordingly, it would be desirable to provide a system for accurately locating the blood vessel wall for properly placing a hemostasis plug over a puncture site.

SUMMARY OF THE INVENTION

According to one aspect of the present invention, an apparatus useful for inhibiting blood loss out a puncture site in a blood vessel wall and for indicating the location of a blood vessel comprises a vent tube including a tubular shaft having a proximal end, a distal end, and a lumen extending longitudinally between the proximal end and the distal end, and a control head on the distal end of the vent tube shaft, the control head including a proximal end portion, a distal end portion having a distal port, and a central portion between the proximal end portion and the distal end portion, the control head including a lumen extending from the distal port to the vent tube shaft lumen.

According to another aspect of the present invention, a pledget delivery and blood vessel puncture site control system comprises a control tip including a vent tube having a tubular shaft with a proximal end, a distal end, and a lumen extending longitudinally between the proximal end and the distal end, and a control head on the distal end of the vent tube shaft, the control head including an externally tapered proximal end portion, a distal end portion having a distal port, and a central portion between the proximal end portion and the distal end portion, the control head including a lumen extending from the distal port to the vent tube shaft lumen, a pledget pusher positioned around the vent tube shaft, the pledget pusher including a tubular shaft having a proximal end, a distal end, and a lumen extending longitudinally between the pledget pusher proximal end and the pledget pusher distal end, the inner diameter of the pledget pusher lumen being larger than the outer diameter of the vent tube, a delivery cannula positioned around the pledget pusher, the delivery cannula including a tubular shaft having a proximal end, a distal end, and a lumen extending longitudinally between the delivery cannula proximal end and the delivery cannula distal end, the inner diameter of the

delivery cannula lumen being larger than the outer diameter of the pledget pusher, the control head extending distally from the delivery cannula distal end, the delivery cannula distal end extending distally of the pledget pusher distal end.

5 According to another aspect of the present invention, a method of positioning a pledget adjacent to the exterior surface of a blood vessel puncture site in a patient comprises the steps of advancing a control head of a control tip through the puncture site and at least partially into the blood vessel, the control tip including a proximal portion extending out of the puncture site and out of the
10 patient, advancing an assembly over the control tip proximal portion and adjacent to an exterior surface of the blood vessel, the assembly including a delivery cannula having a lumen, a pledget pusher in the delivery cannula, and a pledget in the delivery cannula, proximally retracting the control head to engage the pledget, and expelling the pledget from the delivery cannula.

15 According to yet another aspect of the present invention, a method of measuring the distance between an epidermal outer surface and the outer surface of a blood vessel, the blood vessel having a puncture therethrough at a puncture site, comprises the steps of advancing a control tip through subcutaneous tissue
20 and into the blood vessel through the puncture, advancing a tubular shaft over the control tip until a distal end of the tubular shaft engages the outer surface of the blood vessel, and positioning a marker along the tubular shaft against the epidermal outer surface.

25 According to yet another aspect of the present invention, a method of at least partially controlling blood flow through a puncture site in a blood vessel wall comprises the steps of inserting a control tip through the vessel wall at the puncture site and at least partially into the blood vessel, and positioning a pledget

004240" 029T2960

adjacent to an outer surface of the blood vessel wall at the puncture site with the control tip still at least part in the vessel puncture site.

Still other objects, features, and attendant advantages of the present invention will become apparent to those skilled in the art from a reading of the following detailed description of embodiments constructed in accordance therewith, taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention of the present application will now be described in more detail with reference to preferred embodiments of the apparatus and method, given only by way of example, and with reference to the accompanying drawings, in which:

Fig. 1a illustrates a first exemplary embodiment of a control tip in accordance with the present invention;

Fig. 1b illustrates a second exemplary embodiment of a control tip in accordance with the present invention;

Fig. 1c illustrates an enlarged cross-sectional view of a third exemplary embodiment of a control tip in accordance with the present invention, taken at line 1-1;

Fig. 1d illustrates an enlarged cross-sectional view of a third exemplary embodiment of a control tip in accordance with the present invention, taken at line 1-1;

Fig. 2 schematically illustrates portions of a system in accordance with the present invention positioned in a blood vessel of a patient;

Fig. 3a illustrates a side elevational view of portions of a first exemplary system in accordance with the present invention;

Fig. 3b illustrates an enlarged cross-sectional view of a portion of the exemplary embodiment of a pusher illustrated in Fig. 3a in accordance with the present invention;

5 Fig. 4 schematically illustrates portions of the first embodiment, illustrated in Fig. 3a, positioned in a blood vessel of a patient;

Fig. 5 illustrates a side elevational view of portions of a second embodiment of a system in accordance with the present invention;

Fig. 6 schematically illustrates portions of the second embodiment, illustrated in Fig. 5, positioned in a blood vessel of a patient;

10 Fig. 7 illustrates a side elevational view of a system in accordance with the present invention;

Figs. 8a-8f illustrate steps of an exemplary method in accordance with the present invention;

15 Fig. 9 illustrates a cross-sectional view of a pledget hydration chamber in accordance with an exemplary embodiment of the present invention;

Fig. 10 illustrates the chamber of Fig. 9 with portions of a device of Fig. 7;

20 Figs. 11-13 illustrate exemplary steps of hydrating, preparing, and positioning a pledget into a delivery device in accordance with an exemplary embodiment of the present invention;

Fig. 14 illustrates a cross-sectional view of yet another embodiment of a control tip device in accordance with the present invention;

Fig. 15 illustrates a cross-sectional view of yet another embodiment of portions of a control tip device in accordance with the present invention;

25 Fig. 16 illustrates a cross-sectional view of yet another embodiment of portions of a control tip device in accordance with the present invention;

Fig. 17 illustrates a cross-sectional view of yet another embodiment in accordance with the present invention;

Fig. 18 illustrates a cross-sectional view of yet another embodiment in accordance with the present invention;

Fig. 19 diagrammatically illustrates a cross-sectional view of yet another embodiment in accordance with the present invention in one preferred use;

5 Fig. 20 diagrammatically illustrates a cross-sectional view of yet another embodiment in accordance with the present invention in one preferred use;

Fig. 21 diagrammatically illustrates a cross-sectional view of yet another embodiment in accordance with the present invention in one preferred use; and

10 Fig. 22 diagrammatically illustrates a cross-sectional view of yet another embodiment in accordance with the present invention in one preferred use.

DESCRIPTION OF PREFERRED EMBODIMENTS

15 Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

20 In the context of the present invention, "pledget" means a piece of sponge formed into a generally elongated shape having a size which allows delivery in a hydrated state through a delivery cannula or introducer to a site of a puncture in a blood vessel.

"Sponge" means a biocompatible material which is capable of being hydrated and is resiliently compressible in a hydrated state. Preferably, the sponge is non-immunogenic and may be absorbable or non-absorbable.

25

"Absorbable sponge" means sponge which, when implanted within a human or other mammalian body, is absorbed or resorbed by the body.

"Hydrate" means to partially or fully saturate with a fluid, such as saline, water, contrast agent, thrombin, therapeutic agents, or the like.

10 15 20 25
1004240-072960
5 10 15 20 25
Figure 1a illustrates a puncture control tip 10 in accordance with a first embodiment of the present invention. The puncture control tip 10 includes a tubular, hollow puncture control tip shaft 14 which function as a flash tube, as described in greater detail below. The shaft 14 includes a lumen 34 (see Figure 1c, for example) which extends longitudinally between proximal and distal ends. For reasons which will be readily appreciated by one of ordinary skill in the art, lumen 34 can optionally be coated or otherwise provided with an interior surface which inhibits blood coagulation. By way of example and not of limitation, the lumen 34 can be coated with material including heparin (e.g., heparinized), tPa, or other functionally similar materials or compounds which inhibit or prevent blood from clotting or otherwise coagulating in the lumen 34.

The puncture control tip 10 includes, at its distal end, a hollow puncture control head 16 mounted or otherwise secured to distal portions of the shaft 14. As illustrated in Figure 1a, the head 16 includes a distal tapered portion 18, a proximal tapered portion 20, and a center portion 22 between the distal and proximal portions which preferably has a constant outer diameter. Both of the portions 18 and 20 can alternatively be a step, rounded shoulder, or the like. The interior of head 16 is open to the exterior of the head at the distal portion 18 (see, e.g., Figures 1c and 1d).

Figure 1b illustrates another embodiment of a puncture control tip 12 in accordance with the present invention. The control tip 12 is similar to control tip 10, but includes a puncture control tip head 24 which includes a hole 26 which communicates the exterior of the head with the interior thereof and functions as a

flash hole or vent for the control tip. According to yet another embodiment, a hole 26' can be included in addition to, and preferably instead of, hole 26. Hole 26' is formed in the shaft 14 proximal of and proximate to the proximal portion 20, and communicates the interior lumen of the shaft with the exterior of the shaft.

5 Turning to Figures 1c and 1d, further embodiments of heads 16 and 24 are illustrated as cross-sectional views taken at line 1-1 in Figure 1b. Shaft 14 includes lumen 34 which fluidly communicates the interior 30 of heads 16, 24 with a proximal end of the shaft. The lumen 34 has an inner diameter selected to be larger than the external diameter of a guidewire, preferably an exchange wire
10 28, used therewith (see Figure 2). Furthermore, a plurality of holes 26 (not illustrated) can be formed in the control head, circumferentially spaced and at the same longitudinal location as hole 26.

As illustrated in Figure 1c, head 16, 24 can be relatively thin walled such
15 that the internal dimensions of the interior cavity 30 is larger in center portion 22 than in the distal 18 and proximal 20 portions of the head. As also described briefly above, the distal portion 18 of head 16, 24 includes a distal port 32 having an internal opening diameter D_1 also selected to be larger, and preferably only slightly larger, than the external diameter of a wire 28 used with the control tip
20 10, 12. While the function of port 32 in conjunction with wire 28 will be described in greater detail below, one aspect of the present invention is that by selecting the external diameter of wire 28 and the inner diameter of port 32 to be only slightly different, blood flow into interior 30 of head 16, 24 is greatly restricted, thus allowing the hole 26 to be the sole entrance into the control tip for
25 blood to flow up shaft 14 to indicate that the control tip head has been located in a blood vessel. As illustrated in Figure 1d, the head 16, 24 can be formed with a thick wall, such that the interior chamber 30 is the same size as port 32.

004220-072960

5 *Ans. a3* Preferably, the control tip is formed of a flexible, biocompatible material, such as a thermoplastic. by way of example and not of limitation, the material out of which the control tip is formed has a Shore hardness between about 90A-82D, preferably between about 98A-74D, more preferably about 64D.

10 Turning now to Figure 2, some functions of control tips in accordance with the present invention can be better appreciated. As discussed above, at the end of a endoluminal, transvascular procedure the practitioner will oftentimes want to seal the access point to the patient's vasculature. As is commonplace when using a Seldinger technique for vascular access, a guidewire, exchange wire, or guide catheter remains in the patient's blood vessel 5 at the end of the procedure. The indwelling device extends through the epidermis layer 1, through the subcutaneous layers 3, and enters the vessel wall 7 at a puncture site 9.

15 A control tip 12 (as illustrated in Figure 2, although control tips 10 can also be used) is advanced either through an indwelling guide catheter, or over an indwelling wire 28, until blood B enters hole 26. The blood B flows into interior 30 of the control head 24, through lumen 34 and around the wire 28, and exits the shaft 14 at its proximal end. This flash of blood at the proximal end of shaft 14
20 gives the practitioner a visual indication that the control tip is seated in the puncture site 9, while the placement of the hole 26 distal of the proximal portion 20 assists in maintaining the puncture site closed during the procedure. As discussed above, because port 32 has an inner diameter selected to be only slightly larger than the outer diameter of wire 28, little or no blood enters into the interior
25 30 of the head 24 between the wire and port. Also, the distance between the hole 26 and the proximal end of the vent tube 14, and the internal diameter of the vent tube, are selected together to prevent a capillary effect by the inner wall of the vent tube from stopping blood flow while still permitting good flexibility of the

004220" 07292960

vent tube. Additionally, the vent tube 14 can optionally be formed to have a flexibility which changes along its length, e.g., is more flexible at distal portions than at proximal portions. While a gradual distal increase in flexibility is preferred, the change can be more abrupt, such as by forming the vent tube 14 of two distinct tubes of different flexibilities, although this later embodiment is less preferred.

Figure 3a illustrates an embodiment of a depth marker 36 mounted over a control tip 12 in accordance with the present invention. Marker 36 is a hollow, tubular member preferably shorter than the control tip 12. Marker 36 optionally further includes a collar 38 slidable along the outer surface of the marker. The collar 38 is preferably elastic such that it will engage the exterior of the marker 36 to hold its position on the marker, yet be movable along the marker upon the application of a small force to slide the collar along the marker. Thus, collar 38 can be used as a depth indicator, as described in greater detail below.

The marker 36 includes a proximal end 40, a distal end 42, and an interior lumen 44 extending longitudinally between the proximal and distal ends. The proximal and distal ends of the marker 36 preferably include a seal with the shaft 14 of the control tip 12. The seal between the shaft 14 and the marker 36 can be formed in any suitable way that provides a fluid seal between the marker and the shaft. By way of example and not of limitation, the proximal and distal seals can be formed by forming the marker with a reduced inner diameter at (at least) the proximal and distal ends of the marker, or by including dynamic sealing members, such as O-rings or septa. Preferably, at least the distalmost portions of distal end 42 is slightly rounded to prevent trauma to the vascular tissues with which it comes into contact.

Marker 36 is preferably attached to control tip 12, or less preferably, positioned on the control tip 5 so that it is difficult to slide them longitudinally relative to each other. The distal end 42 is spaced from the elongated central portion 22 of the control head by a distance X, described in greater detail below.

Optionally, the control tip and the marker can be interconnected using a releasable proximal connection, e.g. a Touhy-Borst connector (for which the marker would include cross-drilled holes or the like for blood flash), ultrasonic welding, glueing, etc.

Figure 3b illustrates an enlarged cross-sectional view of a distal end of a marker 36 or 46 in accordance with the present invention. The marker includes an interior lumen 44 which terminates at the distal end 52 of the marker with a countersunk tapered distal port. For reasons which will be explained in greater detail below with reference to Figures 5 and 6, the taper of the distal port relative to longitudinal axis A is selected to be very similar to that of the proximal tapered portion 20 of head 16, 24. This aspect of the present invention permits the wall of the marker 36, 46 which forms the port, together with the proximal tapered portion 20, to function as a valve in a manner similar to a needle valve.

Figure 4 illustrates a control tip 12 used together with a depth marker 36 to control a puncture site 9. When the control tip 12 has been located in the puncture site 9, as shown by the blood flash B out the proximal end of flash tube 14, with the marker 36 on the shaft 14 the practitioner feels the additional resistance offered by the vessel wall 7 to further advancement of the marker upon distal advancement of the control tip/marker assembly. As the distal end 42 of the marker 36 forms a seal with the shaft 14, the distal end 42 can then be used to control the flow of blood out of the puncture site 9, and the control head 24 is pushed slightly distally into the blood vessel 5. Collar 38 can be positioned

against the epidermis 1 when the distal end 42 is at the puncture site 9, which permits the collar 38 to mark the distance between the distal end of the marker 36 and the outer surface of the epidermis, thus functioning as a depth indicator of the puncture site.

5

Turning now to Figures 5 and 6, yet another embodiment in accordance with the present invention is illustrated. Figure 5 illustrates a control tip 10 with head 16 and a marker 46 mounted thereover. Marker 46 is similar to marker 36, described above, but does not include seals at its proximal 50 and distal 52 ends. A lumen 48 extends longitudinally through the marker 46 between the proximal and distal ends and forms an annular space or lumen 54 between the flash tube or shaft 14 and the marker 46. According to a preferred embodiment of the present invention, distal end 52 is tapered as illustrated in Figure 3b. Marker 46 is affixed to control tip 10 in a fashion similar to marker 36 and control tip 12, described above.

10
15

Figure 6 illustrates a marker 46 used in accordance with one aspect of the present invention with a control tip 10. While control tip 12 can also be used, the function of flash hole or holes 26 is assumed by the combination of proximal tapered portion 20 of head 16 and the distal end 52 of marker 46, optionally further including a tapered countersunk port therein. In a manner similar to that described above with reference to Figure 4, the marker 46 can be used to control puncture site 9. By moving the assembly of the control tip 10 and the marker 46 longitudinally, the distal end 52 of the marker 46 and the proximal tapered portion 20 of the head 16 can be used to throttle the flow of blood into the annular lumen 54 in a manner similar to a needle valve. That is, by drawing the head 16 closer to the puncture site 9, the flow cross-sectional area is made smaller, thereby reducing the flow of blood into the lumen 54, and pushing the assembly distally

20

25

increases the flow area, increasing the flow of blood. As the proximal end 50 is not sealed with shaft 14, blood flash B can be observed out of the proximal end of the marker 46, indicating that the marker is in fluid communication with the blood vessel 5. Furthermore, as wire 28 and port 32, as described above, permit little or no blood to flow into lumen 34 of the shaft 14, the blood flash B at proximal end 50 can be a reliable indicator that the blood vessel has been accessed.

In the embodiments of Figures 3a-6, it is preferable that the distal end of the depth marker has significant radial or lateral clearance from the control tip shaft, so that the two elements will move laterally relative to each other near the marker's distal end, which promotes tactile feedback to the practitioner when the control tip enters the blood vessel.

Figure 7 illustrates a side elevational view of a system in accordance with the present invention. The system generally includes a control tip 10 or 12, a pledget pusher 37, a delivery cannula 56, a pledget 90, and a proximal handle 62. As illustrated in Figure 7, pledget 90 is positioned in a lumen 58 in delivery cannula 56 and around shaft 14 of control tip 12. Pusher 37 is also positioned in lumen 58, and has a length such that, when the pusher is in a retracted, proximal position illustrated in Figure 7, the distal end 42, 52 of the pusher is proximal of the distal end of the delivery cannula 56. A pledget 90 is positioned in the distal portion of the lumen 58 distal of the distal end of the pusher 37 so that the pusher can push the pledget distally out of the delivery cannula. Pledget pusher 37 is structurally very similar to either pusher 36 or pusher 46, but is not attached to the control tip 10, 12 over which it longitudinally slides.

The pledget 90 according to one preferred embodiment of the invention is formed from a sheet of absorbable sponge material which has been cut into a

rectangular shape and rolled to form a compact, substantially cylindrical, elongated pledget. One type of absorbable sponge material which is acceptable for use in the present invention is Gelfoam™, manufactured by the Pharmacia & Upjohn Company. Gelfoam™ is a porous, pliable, cross-linked gelatin material and is available commercially in sheet form as pre-compressed or non-compressed sponge. The material may be provided preformed as a pledget 90 or may be cut with a punch, or a stencil, or template and knife and rolled to form a pledget. Once hydrated, the pledget 90 can be easily compressed to fit into a lumen having a smaller cross sectional area than the original cross sectional area of the pledget. Additionally, the kneading of the hydrated pledget 90 during delivery encourages air trapped within the Gelfoam™ to be expelled and replaced with fluid, allowing rapid expansion upon delivery. When a pledget 90 of a pre-compressed Gelfoam™ is hydrated and kneaded (expelling air) during delivery, the pledget will have the absorption capacity to rapidly expand to many times (e.g., 3 or more times) its original dry volume upon delivery. When a pledget 90 of the non-compressed Gelfoam™ is hydrated and kneaded (expelling air) during delivery, the pledget will have the absorption capacity to rapidly expand to its original dry volume upon delivery. These properties make the Gelfoam™ sponge material particularly useful for facilitating hemostasis of puncture sites by injection.

The delivery cannula 56 includes a proximal hub 60. Hub 60 includes mating structures to mate with corresponding mating structures formed in a distal hub 76 of handle 62. By way of example and not of limitations, the mating structures of hub 60 and hub 76 can be luer fittings, screw threads, releasable bayonet fittings, and any other fitting which can releasably connect together hubs 60, 76 so that the delivery cannula 56 and the handle 62 can be moved together when the structures are mated, and the delivery cannula and handle can be separated and moved independently when the structures are released.

00621670-072400

Pusher 37 includes a proximal hub 78 which both limits the proximal and distal movement of the pusher, and provides an enlarged section at which a practitioner can grasp the pusher if necessary. Hub 78 optionally further includes a proximal outwardly flared stop 80 which limits longitudinal motion of the pusher 37 relative to the handle 62 and other structures of the system, described in detail below. More particularly, stop 80 limits distal motion of the pusher 37, because it has an outer dimension (e.g., diameter) larger than portions of hub 76 of handle 62, and limits proximal motion because the stop is longitudinally aligned with portions of a motion limiting device 82 (described below) positioned proximal of the stop.

Handle 62 generally provides a place for a practitioner to grasp and manipulate the control tip 12, pusher 37, and delivery cannula 56 together, while also permitting the practitioner to separately move these individual components. Therefore, while a particular embodiment of a handle in accordance with the present invention is illustrated in Figure 7, the present invention relates more generally to structures which performs these functions.

Handle 62, as illustrated in Figure 7, includes a first side 64, a second side 66, and an open interior space 68. By providing handle 62 with an open construction, such as that illustrated in Figure 7, a practitioner is able to access the proximal portions of pusher 36, 46 and control tip 12 in order to manipulate these elements. Each of the sides 64, 66 includes a wing 70, 72, respectively, which is optionally further provided to provide a bearing surface for a practitioner to pull the handle and any attached elements proximally.

The proximal end of the handle 62 includes an opening, slot, or the like 74 which receives a proximal motion limiting device 82 for the control tip 12. In the

embodiment illustrated in Figure 7, device 82 includes a proximal flange 84 which extends radially beyond the extent of opening 74, and therefore limits distal motion of the device 82 as it slides in the opening 74. The device 82 also includes a central cylindrical portion 86 which longitudinally slides in opening 74. A distal bumper 88 of device 82 is also radially larger than opening 74, and limits proximal motion of the device 82 relative to the handle 62. The flash tube or shaft 14 is secured to and preferably extends proximally through device 82, as illustrated in Figure 7. Thus, the entire control tip 12 is permitted to move longitudinally over a limited range delimited by the proximal flange 84 and the distal bumper 88. Because the control tip 12 is therefore permitted to move longitudinally over only a limited range defined by device 82, and handle 62 is attached to delivery cannula 56 via hubs 60 and 76, the control tip is capable of moving longitudinally over only a limited range relative to the delivery cannula. The magnitude of range X (see Figures 3a, 5, and 8A) is between about 0.025 inches (0.06 cm) and about 0.25 inches (0.6 cm), preferably between about 0.1 inches (0.25 cm) and about 0.2 inches (0.51 cm), and more preferably about 0.15 inches (0.38 cm).

As will be readily appreciated by one of ordinary skill in the art, device 82 can take forms different from those illustrated in Figure 7, while still performing the functions describe above. By way of example and not of limitation, device 82 and handle 62 can include other types of complementary surfaces, including mating threads, tabs and slots, and the like, within the scope of the present invention. Furthermore, opening 74 can be formed open on one lateral side, so that device 82 can be snapped into the handle 62 in a direction into or out of the plane of view of Figure 7, thereby permitting assembly and disassembly of the handle with the other elements of the system. To facilitate this assembly and disassembly, it is advantageous to form at least the proximal portions of handle 62

of a resilient material which will deform to permit the device 82 to be snapped into the handle.

004220"072400 09621670

Figures 8a-8f illustrate a system as illustrated in Figure 7 used in accordance with an exemplary embodiment of the present invention. After an endoluminal procedure which has been performed using, in part, a Seldinger technique for access to the patient's vasculature, a wire 28 is advanced into the patient's blood vessel 5 through a puncture site 9 in the vessel wall 7. A control tip 12, pusher 37, delivery cannula 56, handle 62, and pledget 90 are advanced together over the wire 28, as illustrated in Figure 8a. According to a less preferred embodiment, the control tip is first advanced over the wire and into the blood vessel, and thereafter the delivery cannula, handle, pusher, and pledget are advanced over the control tip. As the practitioner advances the system along the wire 28, the control head 24 passes through the puncture site 9. Because the vessel wall presents more resistance to the control head than the subcutaneous tissues 3, the practitioner can feel when the control head has reached the outer portions of the puncture site 9. The practitioner then advances the control head further into the patient and into the blood vessel 5.

When the hole 26 enters the blood vessel 5, blood B flashes out the proximal end of flash tube 14, as described above, indicating to the practitioner that entry to the blood vessel has been made. Because blood may have previously been present in lumen 34 of shaft 14, and therefore potentially has already clotted or coagulated, blocking the lumen 34, it is preferable that lumen 34 be coated with a blood anticoagulant, as described above. Another tactile indication to the practitioner that entry to the blood vessel 5 has been made is provided by the distance or gap X between the proximal end of the control head 24 and the distal end of the delivery cannula 56. Because the overall flexibility of the system

between the proximal end of the control head 24 and the distal end of the delivery cannula 56 is less than both the longitudinally adjacent sections of the system, the practitioner can feel that the system is more easily moved laterally when the control head 24 is in the position illustrated in Figure 8a. Conversely, when the practitioner does not feel this reduced resistance to lateral movement of the system, the practitioner has an indication that the blood vessel 5 has not been properly accessed.

Figure 8b illustrates a stage in the exemplary method later than that illustrated in Figure 8a. After the practitioner has accessed the blood vessel 5 as described above, the entire system is advanced down the wire 28, as suggested by the arrow in the figure. Advancement of the system is halted when the distal end of the delivery cannula 56 engages the outer portions of the puncture site 9. As described above, as the vessel wall 7 provides more resistance to advancement of the system than does the adjacent subcutaneous tissues, the practitioner can feel when the delivery catheter has engaged the vessel wall. Verification that the delivery catheter is properly engaged against the vessel wall 7, and not merely hung up on a somewhat more resilient anatomical structure within the subcutaneous tissues, is provided by blood flash out the proximal end of the flash tube 14. At this point, the puncture site 9 is controlled by the delivery cannula 56.

Figure 8c illustrates a stage in the exemplary method later than that illustrated in Figure 8b. After the delivery cannula has engaged the outer surface of the puncture site 9, the device 82 (described above) is pulled proximally relative to the handle 62 while the remaining elements of the system are held stationary. The control tip 12, including the control head 24, is retracted proximally and engages the inner surface of the vessel wall at the puncture site 9. Thus, both the interior and exterior surfaces of the vessel wall 7 are engaged by

portions of the system, which controls blood flow out of the puncture site. As discussed above, access to device 82 is facilitated by the open structure of handle 62, permitting a practitioner to more easily pull the device 82 proximally relative to the handle 62. Additionally, as the control head 24 is positioned distally of the
5 pledget 90 and controls access to the blood vessel through the puncture site 9, the pledget is inhibited, and preferably prevented, from entering the blood vessel. Thus, the present invention is also advantageous because it can be used to prevent introduction of all or portions of a pledget into the bloodstream of a patient, which could otherwise initiate a clotting sequence in the blood vessel, with predictably
10 hazardous consequences to the patient.

Figure 8d illustrates a stage in the exemplary method later than that illustrated in Figure 8c. The handle 62, delivery cannula 56, and control tip 12 have been retracted proximally, while holding stationary the pusher 37, such as by
15 pulling proximally on the distal portions of bumper 88 while engaging the proximal portions of stop 80 to prevent its longitudinal motion. Proximal retraction of the delivery cannula 56 relative to the pusher 37 causes distal portions of the pledget 90 to be exposed, while at the same time the pusher does not move and is left positioned at the exterior surface of the blood vessel 5 at the
20 puncture site 9. At the same time, proximal portions of the control head 24 are drawn through the distal portions of the pledget 90. It is preferable that the handle 62, delivery cannula 56, and control tip 12 are moved only part of the distance necessary to completely expose the pledget 90 and for stop 80 to engage portions of hub 76, as illustrated in Figure 8d, so that the pledget can be expressed and
25 compressed, as described below with reference to Figure 8e.

Figure 8e illustrates a stage in the exemplary method later than that illustrated in Figure 8d. While holding handle 62 stationary relative to the patient,

the pusher 37 is advanced distally down the control tip 12, which expels or pushes the remainder of the pledget 90 out of the lumen 58 and simultaneously compresses the pledget against the external surface of the blood vessel wall 7 at the puncture site 9. During this expulsion process, the control head 24 is positioned in the puncture site 9, and therefore at least inhibits, and preferably prevents, the pledget 90 from being pushed into the blood vessel 5. In this manner, the puncture site 9 is controlled throughout the steps of positioning the pledget 90 adjacent to the exterior of the puncture site and both inhibits bleeding and inhibits the introduction of material, including the pledget 90 as well as tissue fragments, into the blood vessel.

Figure 8f illustrates a stage in the exemplary method later than that illustrated in Figure 8e. The handle 62 is released from its connection with the delivery cannula 56 by releasing the connection between hub 76 and hub 60. The handle is then retracted proximally, carrying with it the control tip 12 and the pusher 37. The delivery cannula 56 is preferably held stationary in the patient during this retraction, so that the delivery catheter can hold the pledget 90 in place. As the control head 24 is pulled out of the puncture site 9, the site is compressed by the pledget 90, which inhibits bleeding and promotes closure of the puncture site. As the control tip 12 is further retracted, the control head 24 is drawn through the pledget, while the delivery cannula inhibits the pledget from following the control tip back up into the delivery cannula. The handle, pusher, and control tip are then completely removed. Then, the delivery cannula is removed, preferably slowly and with the application of localized compression to the epidermis above the puncture site, leaving the pledget 90 in place to promote healing of the puncture site 9 and inhibit blood flow from the blood vessel.

Also illustrated in Figure 8f is an exemplary embodiment of the mating structures of hubs 60 and 76 which releasably hold together the handle 62 and the delivery cannula 56. As illustrated in Figure 8f, hub 60 includes a mating structure 92, e.g., a tubular extension 94 including a tab 96 extending radially therefrom. Hub 76 includes an internally threaded collar 96 which receives the extension 94 therein and secures the two elements together.

Figure 9 illustrates an exemplary embodiment of a pledget loading device 100 useful for preparing a pledget 90 and loading the pledget into a delivery cannula. As illustrated in Figure 9, the pledget loading device 100 includes a body 102 having an interior chamber 104. A tubular receiving element 106 extends distally from the distal end of the body, and includes a lumen 116 therein communicating the interior chamber 104 with the exterior of the body. A fluid coupling 108 extends proximally from the end of the body opposite the element 106, and includes a flange, tab, or the like 112 and an internal lumen 114 which communicates the interior chamber 104 with the exterior of the body. The flange 112 is structured to releasably mate with a corresponding structure on a high pressure fluid delivery device, e.g., a syringe with a luer fitting. The body 102 also includes a stop 110 positioned in the lumen 116 which prevents a delivery cannula of a size greater than the internal dimension of the stop from entering into the chamber 104.

Figure 10 illustrates the pledget loading device 100 with a delivery cannula 56, pusher 37, and a control tip 12 inserted into the tubular receiving element 106. As described above, stop 110 is sized so that the delivery cannula 56 is prevented from entering into the chamber 104, and preferably forms a fluid seal with the stop 110, the inner surface of the element 106, or both. The pusher 37 and the control tip 12 extend into the chamber 104. The combination of the tapered

countersunk distal end 52 of the pusher and the tapered proximal portion 20 of the control head 16, 24 form a fluid control member 118 which operates in a manner similar to a needle valve. The operation of fluid control member 118 will be described in greater detail below.

5

004220-072400
09621670-072400

In Figure 11, a cylindrical pledget 90 has been inserted into the chamber 104. The pledget can be placed in the chamber 104 before or after the control head 16, 24 is positioned in the chamber. A source of hydration fluid, such a syringe (not illustrated), is coupled to fluid coupling 108, and hydration fluid F is injected into the chamber 104. Air in the chamber 104 is allowed to escape through fluid control member 118, while the pledget 90 is retained in the chamber and hydrated. As illustrated in Figure 12, to assist in hydrating the pledget 90, the pusher 37, is retracted into the lumen 58 of the delivery cannula 56, in effect opening the fluid control member 118. Air and hydration fluid are then allowed to flow past the stop 110, through the lumen 58, through the lumen 39 of pusher 37, and out of the system. As illustrated in Figure 13, the further introduction of high pressure fluid into chamber 104 forces the hydrated pledget 90 past the stop 110 and into the portion of lumen 58 not occupied by the pusher 37, while hydration fluid continues to flow out the lumen 39. In this manner, the hydrated pledget 90 is loaded into the end of the delivery cannula 56.

10
15
20

Figure 14 illustrates yet another embodiment of a control head in accordance with the present invention. As illustrated in Figure 14, a constant outer diameter guidewire 120 is slidingly received in the tapered distal portion 20 of a control tip 24. At the distalmost end of the distal portion 20, the guidewire 120 and the tapered portion 20 are nearly the same size, so that there is little or no blood flow into the interior 30 of the control head 24 past the guidewire. Such an

25

arrangement helps assure that any blood flow into the flash tube 14 (see Figures 1a-1d) enters the control head 24 through the hole 26.

Figure 15 illustrates yet another embodiment in accordance with the present invention. The proximal end of shaft 14 is fitted with a removable insertion tip 130 so that the proximal end of the shaft, with the tip 130 mounted in the shaft as illustrated in Figure 15, can be backloaded through a pledget (not illustrated) held within a distal end of a delivery cannula (not illustrated). The insertion tip, in the embodiment illustrated in Figure 15, includes a shank 132 and a head 134 attached to the shank. The shank has an outer dimension (e.g., diameter) sized to be received in the lumen 34 of the shaft 14, and can be large enough to form an interference or press fit with the shaft. The shank 132 and the head 134 meet at a shoulder 136 which abuts the proximalmost end of the shaft 14. The head preferably includes a pointed or otherwise tapered tip 138 which assists in moving portions of the pledget radially outward when the shaft and insertion tip 134 are pushed longitudinally through the pledget.

Figure 16 illustrates yet another embodiment in accordance with the present invention. A stylet 150 is inserted through a control tip 10 or 12 and assists in inserting the control tip through a pledget (not illustrated) positioned inside a delivery cannula (not illustrated). The stylet 150 includes a head 152 and a shaft 154 connected to and extending from the head. The shaft 154 is sized to slide through the control tip and shaft 14. The head 152 is enlarged to facilitate pushing on the head to push the proximal end of the shaft 14 through a pledget; the shaft 154 extends from the proximal end of the shaft to assist is radially parting the material of the pledget.

Figure 17 illustrates yet another embodiment in accordance with the present invention, in which a delivery cannula 160 includes a control tip 168 integral with the delivery cannula. The delivery cannula 160 has a tubular wall 162 which extends longitudinally between a proximal end 162 and a distal end 164, which distal end is preferably rounded to ease its insertion through subcutaneous tissues and limit trauma to the vascular wall when it is pressed against it. A lumen 166 extends through the delivery cannula 160 between the proximal end 162 and the distal end 164, and is sized in a manner similar to the other embodiments described herein to receive a pledget, pledget pusher, and/or wire.

Formed integrally with the delivery cannula 162, the control tip 168 extends longitudinally between a proximal end 170 and a distal end 172 radially offset from the center longitudinal axis of the lumen 166. The control tip 168 includes a longitudinally extending lumen 174 and a vent port or hole 176 similar to hole or holes 26. As in other embodiments described herein, the distal end 172 is preferably tapered, and preferably has an inner diameter which tapers distally, as at 178, to form a dynamic seal with a wire (not illustrated) over which the control tip 168 is inserted. As illustrated in Figure 18, the external taper 180 of the distal end of the control tip 168 can extend proximally toward the delivery cannula 160, and the vent hole 176 is preferably formed in this tapered section. Less preferably, however, the vent hole 176 can be formed in the untapered portion 182 within the scope of the present invention.

Figure 19 illustrates yet another embodiment in accordance with the present invention. A depth marker 190 is similar to the delivery cannula 160 having the integral control tip 168, but does not include a lumen 166. A collar 38 is positioned on the outer surface of the depth marker, and permits the user to

record the depth of the blood vessel 5 relative to the outer surface of the epidermis 1. The depth marker 190 is otherwise used in the same manner as the other embodiments of depth markers described herein.

5 Figure 20 illustrates yet another embodiment in accordance with the present invention. A biaxial delivery cannula 200 includes a lumen 202 sized to receive a pledget 90 and a pledget pusher or piston 204 which extends proximally out of the delivery cannula 200. The delivery cannula 200 also includes an integral control tip 206 having a longitudinally extending through lumen 210
10 extending from the control head 208 proximally to the proximal end of the delivery cannula in a manner similar to other embodiments described herein. The lumen 210 is sized to slidably receive the wire 28, and preferably forms a seal with the wire 28 as also described elsewhere herein.

15 The delivery cannula 200 further includes a vent lumen 212 laterally offset from the lumen 202 and the lumen 210, and preferably between the lumens 202, 210. In a fashion similar to that previously described herein, the vent lumen 212 permits blood to flash to the proximal end of the delivery cannula 200 to give a visual indication of when control of the puncture site 9 is made and lost.

20 Figure 21 illustrates yet another embodiment in accordance with the present invention. The embodiment illustrated in Figure 21 is similar in some respects to the embodiment illustrated in Figure 7. A delivery cannula 56, control tip 10 or 12, pledget 90, pusher 37, and wire 28 are similar or the same as
25 described above, and are used in combination with a coaxial vent tube 220 which extends longitudinally through the pusher 37 and the pledget 90. The vent tube 220 includes a longitudinally extending lumen 222 which is sized to receive the control tip 10, 12 therein with an annular clearance to permit blood to flash

proximally through the vent tube 220. Because the vent tube 220 performs the function of permitting blood flash, the shaft 14 of the control tip 10, 12 can be formed without a lumen 34, and can be dimensioned with a smaller outer diameter to increase the annular clearance between the shaft and the vent tube 220. The shaft 14 preferably maintains its relative flexibility to permit the tactile feedback previously described herein. The embodiment illustrated in Figure 21 is used in a manner otherwise similar to those previously described herein.

Figure 22 illustrates yet another embodiment in accordance with the present invention. As illustrated in Figure 22, a vent tube 230 can be used with a control tip 10, 12 so that the vent tube and control tip are advanced laterally next to each other to the puncture site 9. The vent tube 230 permits blood to flash proximally to give a visual indication of when control of the puncture site 9 is made and lost by the control head of the control tip.

For all of the embodiments of the control tip herein, the outer diameter of the central portion is between about 5 French and about 9 French, preferably between about 6 French and about 7 French. The length of the control head, between the distalmost end and the proximal end of the proximal tapered portion, is between about 1.5 inches (3.8 cm) and about 3 inches (7.6 cm), preferably between about 1.5 inches and about 2 inches (6.4 cm), and more preferably about 1.875 inches (4.8 cm). Control heads of these dimensions are well suited for controlling puncture sites as described herein, particularly puncture sites used during Seldinger-type vascular access.

The transverse cross sectional profile of all of the foregoing structures can be any desired shape, including square, oval, triangular, and preferably circular. The materials out of which the control tip, pledget pusher, and delivery cannula

are constructed are preferably selected to be relatively rigid and biocompatible, and more preferably are biocompatible polymers, biocompatible metals and metal alloys, and combinations thereof.

- 5 While the invention has been described in detail with reference to preferred embodiments thereof, it will be apparent to one skilled in the art that various changes can be made, and equivalents employed, without departing from the scope of the invention. All of the aforementioned documents are incorporated by reference in each of their entireties herein.

09621570-072400